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MINISTRY OF AGRICULTURE, FISHERIES AND FOOD

FOOD STANDARDS COMMITTEE REPORT ON ANTIOXIDANTS IN FOOD





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1963

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Food Standards Committee

The terms of reference of the Food Standards Committee are:

To advise the Secretary of State for Scotland, the Minister of Agriculture, Fisheries and Food, the Minister of Health, and as respects Northern Ireland the Secretary of State for the Home Department, on the composition, description, labelling and advertising of food with particular reference to the exercise of the powers conferred on Ministers by Sections 4, 5 and 7 of the Food and Drugs Act, 1955, and the corresponding provisions in enactments relating to Scotland and Northern Ireland.

The members of the Food Standards Committee are :

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Food Additives and Contaminants Suh-Committee The terms of reference of the Food Additives and Contaminants Sub-

Committee are: To consider problems referred to the Suh-Committee by the Food Standards

Committee in relation to all substances added to food, whether deliherately or not. The following served on the Food Additives and Contaminants Sub-

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FOOD STANDARDS COMMITTEE

Report on the Review of the Antioxidant in Food Regulations, 1958

The Food Standards Committee have considered and adopted a Report by their Food Additives and Contaminants Sub-Committee on the review of the Antioxidant in Food Regulations. The Report is as follows:

I. INTRODUCTION

1. We were asked to review the Antioxidant in Food Regulations. 1998 and to consider whether, and to what extent, amendments were necessary. We were also asked to consider and advise on the representations received as a result of the announcement of the review and particularly to consider if the regulations ought to be amended to include official specifications for the permitted antioxidants and, if so, what these specifications afound by.

2. We have come to the conclusion that the scope and form of the present regulations are satisfactory and that there is no need for any primary amendment. We have borne in mind in our review the general principle that an antioxidant shoulded only be also that the satisfactory and the satisfactory of th

II. CONSIDERATION OF THE ANTIOXIDANTS AT PRESENT PERMITTED

3. We saked our Pharmacology Pauli to reconsider the antioxidants at preent permitted and we include the substance of their action, which we have adopted, at Appendix I. Although they act the substance of their action, which we have adopted at the hazard to bealt may unlikely to arise from the confined that hazard to bealt may unlikely to arise from the confined use of burylated hydrocynnoise (B.H.A.) and propy; completely they concluded that hazard to bealt may unlikely to arise from the confined use of burylated hydrocynnoise (B.H.A.) and propy; continued that the substance of the substanc

III. CONSIDERATION OF REPRESENTATIONS FOR ADDITIONS TO THE LIST OF PERMITTED ANTIOXIDANTS

Dinonyl Citrate

Dimonyl Currate

4. We have received representations, though not from food manufacturers,
that dimonyl citrate should be permitted as an antioxidant. We are not
convinced out only citrate is more effective than several conventions of the convention of the conventi

Nordibydroguaiaretic Acid (N.D.G.A.)

5. We have considered representations that N.D.G.A. should be added to the list. There seems to be no evidence that it is in any way more effective than the antioxidants at present permitted and it does not, therefore, satisfy our criterion of need. We do not, therefore, recommend that it should be permitted.

Erythorbic Acid (Isoascorbic Acid) and its Salts

6. It has been suggested that erythorbic acid (isosacorbic acid) and its salts should either be added to the list of permitted anisoidants or should be excluded from the definition of 'anisoidant'. It was learned that the addition of these substances to food might well visit the determination of addition of these substances to food might well visit the determination of the control of the determination of visit and the control of the determination of visit and the presence of erythorbic acid, we think however that the need to use erythorbic acid is not such as to satisfy our criteria of need particularly in view of the permitted use of assorbic acid. We do not therefore recommend that erythorbic acid and its sociium and poissaium salts be added to the permitted list, not be Revulation. 1938 to allow its use in food.

Diphenylamine and Ethoxyquin

7. Requests have been made for the approval of diphenylamine and ethoxyquin (or 1.2 dihydro-6-ethoxy-2,2,4-trimethylquinoline, the active principle in the proprietary preparation 'stop scald') which are used in other countries for the prevention of common scald of apples and pears during storage. Common scald is said to cause considerable losses especially among stored apples. Since diphenylamine and ethoxyquin may be properly regarded as antioxidants within the definition in the current regulations, their presence in food is forbidden. We have received some evidence that diphenylamine is more efficient than ethoxyquin and that both substances are more effective and cheaper to use than oiled wraps. It was therefore represented that both these substances are needed by the trade and that their presence up to 10 parts per million on apples in the case of diphenylamine and up to 2 parts per million on apples and pears in the case of ethoxyquin should be allowed. The toxicity data provided on both was sufficient for us to reach a conclusion that ethoxyquin is to be preferred. We also concluded that there is no overriding need for two substances to be permitted. We therefore recommend that ethoxyquin only should be allowed at a level of up to 2 parts per million on apples and nears.

IV. CONSIDERATION OF FOODS IN WHICH ANTIOXIDANTS ARE AT PRESENT PERMITTED

- 8. We do not see any reason to alter the list of foods in which antioxidants are at present permitted. We do think, however, that the description: Fessential oils, including their flavouring constituents—isolates and concentrates is ambiguous if not positively misleading. We suggest that it be averaged to read: 'Essential oils and isolates from and concentrates of
- centrates is amorgous it not possively inistending. We suggest that we amended to read: "Essential oils and isolates from and concentrates of essential oils."

 9. We think it important that a provision should be included in the regulations to prohibit the presence of antioxidant, from whatever source,

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in foods intended for infant feeding.

V. CONSIDERATION OF REPRESENTATIONS FOR ADDITIONS TO THE LIST OF SPECIFIED FOODS

General

10. We have received representations that antioxidants should be permitted in the following foods: debytrated points (falkes or powder), breakfast cereals, assauge rusks, dried soup mixes containing meat and mean fat (including chickes), meat and vegetable products, frozer bams, particular frice, dried milk and dried cream for manufacturing purposes, auts, packaged, chopped and commitment comiss, cambination and professional productions and from ground must use of other state. We have due to been saided to consider whether authoritants should be permitted in theiring and the consider whether authoritants should be permitted in theiring.

guin.

11. We have carefully considered these representations but we are not satisfied that a case has been made out on a basis of need for the use of antioxidants in any of these foods or in chewing gum. We do not think that the use of it is a considered to the control of th

Naturally Fatty Foods

12. A somewhat parallel series of representations suggest that there is an anomaly in the present regulations in that they only allow antioxidinate to be used if incorporated in an adule fat and do not allow their use in foods that the control of antioxidants or refined fast was permitted because during processing they are devoted of natural data was permitted because during processing they are devoted of natural for control of the co

Synthetic Vitamins and Products containing Very High Concentrations of Vitamins

13. It has been represented that synthetic vitamins and products containing very high concentrations of vitamins should not be classified under the heading 'vitamin oils and concentrates', but should be dealt with in a separate category. Natural oils, and concentrates prepared from them, usually contain sufficient natural antioxidant to confer stability on the preparations, but, it is suggested, antioxidants must be added in the case of synthetic products. It is further suggested that it would be more logical to relate the level of antioxidant to the vitamin A content than to weight and that the permitted level for these vitamins should be increased and expressed as 10 mg of any mixture of B.H.A. and B.H.T. per 1,000,000 international units of vitamin A. The need for additional antioxidant is confined to the oil soluble vitamins, and to vitamin A in particular. The small amount of experimental data submitted indicates that the vitamin A content of very high potency oils falls rapidly on free exposure to air and that this loss can be prevented by a suitable combination of B.H.A. and B.H.T. The basic maximum of 200 p.p.m. of antioxidant is insufficient to prevent loss of vitamin A and, if the suggestion mentioned above were adopted, it would mean that a preparation containing I million international units per gram vitamin A would be able to have 10-2 mg. antioxidant per gram i.e. the oil would contain 1-02 per cent antioxidant or 10,200 p.p.m. instead of the present maximum of 200 p.p.m. of these antioxidants.

instead of the present maximum of 200 p.p.m. of these autoxidants. 14. We agree that some increase in antioxidant is necessary in products containing very high concentrations of vitamin A, but in view of our recommendation in paragraph 3 above, we could not counternance the use of B.H.T. We consider that any increase in antioxidant content should be governed by the Vannin A poiency only and should be confined to preparagoremed by the Vannin A poiency only and should be confined to preparagotency would be subject to the provisions on antioxidants laid down for vitamin oils and concentrates.

15. We recommend that the regulations be amended to permit preparations containing over 100,000 LU's vitamin A per gram to contain 10 p.p.m. of B.H.A. for each 1,000 LU's vitamin A contained in each gram of the preparation.

VI. MINOR AMENDMENTS TO THE REGULATIONS

Definition of Antioxidant

limits

16. It has been suggested that the definition of antioxidant should make it in quite clear that not only tocopherols but also natural foods containing them should be excluded from the definition. We assume that this is the intention of the present regulation and we do not think any amendment is necessary. This is, however, entirely a matter of legal drafting which we recommend should be considered when amending regulations are being

prepared. Expression of Limits for Permitted Gallates in Terms of Gallic Acid

17. We have been asked to consider wbether there would not be advantages in expressing the limits for gallates in terms of gallic acid since the effective part of the esters is the gallic acid content and since analysis for the purposes of enforcement would be simplified by replacing lengthy quantitative determination of mixtures of gallates by the more economical qualitative determination of mixtures of gallates by the more economical qualitative determination of mixtures of gallates in the continuation. We do not thus the properties of the continuation of th

VII. LEACHING OF ANTIOXIDANTS FROM PLASTIC AND

18. The querion of the possible leaching of small quantities of antioxidants from plantics and other containers has been brought to our notice. Ministers have already asked us to undertake in due course a general review of the properties of the properties of the processing, including the leaching of substances from wrappers. We have this under consideration, but until such a review is made we make no recommendation on this matter in this report on food

VIII. LABELLING OF ANTIOXIDANTS

19. We have not reviewed the regulations which deal with the labelling of antioxidants since the Food Standards Committee is at present engaged in a review of all food labelling regulations.

IX. SPECIFICATIONS

20. In the previous Report on Antioxidants, which was published in 1954, it was recommended that specifications as to the purity of permitted anti-oxidants should be proser/bed. We repeat this recommendation. We can also should be proser-bed. We repeat this recommendation. We can determine the compact of the property of the prope

21. However, in our view, there is a need to supplement the FAO/WHO Standard for BLA. by including a statement of the percontage of the 3-incurred fibe active induced and we recommend accordingly. Further, the limits for arrent in the percentage of the percentage of the statement of the percentage of the percentag

X. REVIEW

22. We recommend that any revised regulations made as a result of this report should be reviewed five years after they are made.

- XI. SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS
- (a) Butylated hydroxytoluene should be withdrawn from the list of permitted antioxidants (para. 3).
 - (b) Erythorbic Acid and its Salts should not be excluded from the definition of "antioxidant" (para. 6).
 - (c) Ethoxyquin should be permitted on apples and pears up to 2 parts per million (para, 7).

 (d) The description of essential oils etc. in the First Schedule should be
 - clarified (para. 8).

 (e) Antioxidants should be prohibited in infant foods (para. 9).
 - (f) Preparations containing over 100,000 LU.'s vitamin A per gram should be allowed to contain 10 p.p.m. of butylated hydroxyanisole for
 - every 1,000 LU.'s vitamin A per gram (para. 15).

 (g) Specifications of purity of permitted antioxidants should be pre-
 - scribed (para. 20).

 (h) Any revised regulations should be reviewed after five years (para. 22).

September, 1963

ESC/FAC/REP. 3.

PROPYL, OCTYL AND DODECYL GALLATES, BUTYLATED HYDROXYANISOLE AND BUTYLATED HYDROXYTOLUENE

INTRODUCTION 1. The Pharmacology Panel was asked to assess the pharmacological data

available for the five scheduled antioxidants which are at present permitted in specified foods by the terms of the Antioxidant in Food Regulations, 1958. These antioxidants are defined in the First Schedule to the Regulations as: n-Propyl gallate (n-propyl 3:4:5-trihydroxybenzoate)

n-Octyl gallate (n-octyl 3:4:5-trihydroxybenzoate)

n-Dodecvl gallate (n-dodecvl 3:4:5-trihydroxybenzoate) Butylated hydroxyanisole (a mixture of 2-terroutyl-4-hydroxyanisole and 3-tertbutyl-4-hydroxyanisole) (B.H.A.)

Butylated hydroxytoluene (2:6 di-terrbutyl-p-cresol) (B.H.T.).

STANDARDS OF COMPOSITION AND SPECIFICATIONS OF PURITY 2. In addition to information supplied by manufacturers, the Panel also had available the British Pharmaceutical Codex (1959) specification for propyl gallate, and the specifications for all five antioxidants as listed in the F.A.O./W.H.O.

"Specifications for Identity & Purity of Food Additives "(1). The Panel notes, "openications for identity & Purity of Food additives (5). The Father invoicing in particular, that commercial preparations of B.H.A. may contain different proportions of the 2-tertiary butyl and 3-tertiary butyl stomers. It seems probable that the previous Food Standards Committee recommendation to permit the use of B.H.A. was based on data for a product which contained a higher proportion of 2-isomer than is present in currently available preparations.

DATA ON TOXICITY TO ANIMALS

Butylated Hydroxyanisole and the Gallates 3. There is very little toxicity data additional to that available in 1958 when the Antioxidant in Food Regulations came into effect. Brown, Johnson and O'Halloran(?) fed albino rats for 2 years on diets containing 0-1 per cent B.H.A. (100 times the maximum normally expected to be found in human food) and Norway Hooded rats for 8 months on diets containing 0-5 per cent B.H.A. The fat containing the antioxidant had been heated to 150° C, for half an hour before incorporation into the diet of the Norway Hooded rats. Growth, food consumption, reproduction, mortality, organ weights and post-mortem pathology were normal.

4. Karplyuk(3) fed rats with B.H.A. and with propyl gallate at levels of 600 mg/kg body weight and 500 mg/kg body weight respectively (one-fifth the LD50) for from 68 to 82 days. No changes were observed in the behaviour of the experimental animals, but growth rates were slightly reduced and there was a reduction in the peroxidase activity of the blood. B.H.A. also caused a reduction in blood catalase activity and, on autopsy, the liver weights of animals fed this antioxidant were higher than those of the controls.

5. Ostby and Gregory Wilder(*) reported the results of feeding Cocker Spaniel pups with B.H.A. for 15 months at levels of 5, 50 and 250 mg per kg body weight per day. Liver injury occurred at the highest dosage.

6. Taking into account both the above data and data previously available, Lessing mio account pour ue nove cana and man proviously available, these are generally satisfactory for propyl gallate, the duration of the experiments was satisfactory for rats, but long-term toxicity tests on guines pigs and on dogs were not carried out for a sufficient period. The data presented for core and doclocyl gallates were confined almost exclusively to feeding tests on aris. In tests on propyl gallate and on B.H.A. have taken into account the possibility that the toxicity of antioxidants may be changed at temperatures used in food preparation, but this information is lacking for octyl and dodecyl gallates.

Butylated Hydroxytoluene

7. Before the publication of the Audioxidant in Food Regulations, 1958, much of the information available on the toxicity of B.H.T. came from the results of extensive experiments carried out by Delchmann, Clemmer, Rakoczy and Banchhare? Their results indicated that the distant loves at whith B.H.T., B.H.A. and the gallates caused abnormal directs in an analysis of the control of the public before the containing up to and including 0.8 per cent B.H.T. had no adverse effects.

Is a first the contained by peckinears and others the six disk contained 1 per cent hard and the total fat content of the dist probably did not exceed 5 per cent by weight. More recently, Brown, Johnson and O'Halloranc') studied the effect by weight. More recently, Brown, Johnson and O'Halloranc') studied the effect by the per cent of 50 per cent added has a subject to the contained to the studied that the studied has a subject to the studied to the st

9. Rerpysid(N) fod rats for from two to three months with daily does of BHT, 8HA, and propy glatial edisorded in lard. The amounts of antioxidant fod were about 0.3 per cent in the dist. Under the conditions of the experiment and the conditions of the experiment and the same of the conditions of the experiment and a harmful action on the liver, disturbing the processes of peoplogical synthesis, cleavage and removal of notinn fats from the liver. Only BHT, except the condition of the conditio

10. Little attention seems to be been egiven to investigation of any possible effect that these antioxidants may have on biochemical (e.g. enzymo) activity. There is evidence that B.H. is metabolised by simple direct conjugation to glucuronides and formation of ethereal subplacts/(0)(9)(9) whereas oxidition of a metally group is necessary before B.H.?. can be similarly metabolised and soft of the confidence of the confiden

CARCINOGENESIS

11. The Panel reported that none of these antioxidants has been fully tested for carcinogenicity according to the requirements of the Panel on Carcinogenic Risks in Food Additives and Pesticides set up by the Chief Medical Officer of the Ministry of Health's Committee on Medical and Nutritional Aspects of Food Policy?

TOXICITY TO MAN

12. Apart from propyl gallate, where 0.5 g, was fed to a buman volunteer for six consecutive days without apparent ill effect(1.9) and B.H.A. where men were given single oral 50 mg. doses(1.9)—no direct feeding tests on humans seem to have been renorted.

SUMMARY

13. (a) Propyl Gallate
Specifications are available. Data on toxicity to animals are generally
satisfactory as regards number of animals and species. Duration of test
is satisfactory for rats hut long-term toxicity tests on guinea pigs and dogs
are not of sufficient duration. The data take into account the effect of

heat on fat containing antioxidant but little attention has been given to the detection of biochemical activity. A test has been carried out on a human volunteer, but none of the tests has been designed to investigate the possibility of carcinogenicity. There is no evidence of gross toxicity. (b) Octyl and Dodecyl Gallates

Specifications are available. Toxicity data are confined almost exclusively to feeding tests on rats and no tests with heated antioxidant were included. Information about possible carcinogenicity is lacking. The somewhat limited data do not show evidence of gross toxicity.

(c) Butylated Hydroxyanisole

Specifications are available. Data on toxicity to animals are generally satisfactory as regards number of animals and species but long-term tests on animals other than rats are not of sufficient duration. The data take into account the effect of heat on the antioxidant and also the possibility that other additives in the diet may have a synergistic effect on toxicity. Information is available on the metabolism of B.H.A. in the rabbit. Little attention has been given to detection of biochemical activity and information about possible carcinogenicity is lacking. The data indicate some degree of long-term toxicity-in particular, liver damage to dogs occurs at high dosage rates.

(d) Butvlated Hydroxytoluene

Specifications for purity are available. Animal experiments showed that B.H.T. was not differentiated from other antioxidants when amounts up to 0-8 per cent were added to a diet containing 1 per cent lard, but was so differentiated when the animal diet contained 20 per cent of lard. The adverse findings were-decreased initial growth rate, increased liver weight relative to body weight and loss of hair under conditions of stress. A small proportion of offspring from rats fed B.H.T. were born without eyes, a phenomenon absent from the controls. From studies of the effect on enzyme systems, B.H.T. was considered to be more toxic than other permitted antioxidants. Metabolic studies show that B.H.T. is eliminated from the animal more slowly than B.H.A. Direct experiments to investigate possible carcinogenesis are lacking. There seems to be no information on the effect on man, but the sum of the information available indicates the margin of safety is less for B.H.T. than for other antioxidants.

SUBSTANCE OF PANEL'S RECOMMENDATIONS

(a) The Gallates and Butylated Hydroxyanisole

Although further tests are required to assess the possibility of carcinogenicity and to evaluate the significance of bio-chemical activity, a hazard is unlikely to arise from the continued use of propyl octyl and dodecyl gallates and of B.H.A. as antioxidants in accordance with the present Antioxidant in Food Regulations.

(b) Butylated Hydroxytoluene

The available information indicates that the margin of safety for B.H.T. is less than for the other permitted antioxidants and its use should be discontinued unless it can be shown to have over-riding technical advantages compared with uniess it can be snown to nave over-rising technical advantages compared with the other permitted antioxidants. This view is reinforced by the cautious attitude towards the use of B.H.T. adopted in the Sixth Report of the Joint FAO./W.H.O. Expert Committee on Food Additives (1962)."). This Expert Committee gave only a conditional acceptable intake level (up to 0.5 mg/kg. body weight) for B.H.T. and proposed that it be used under scientific supervision.

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 - W.H.O. Technical Report Series No. 228, (1962).

| APPENDIX II | Sulphated | Max. 0-05% | Max. 0-05% | Max. 0 : 5%(3) Max. 0 : 05% | not specified |
|--------------|-------------------|---|--|---|--|
| | Loss on Drying | Max. 0·5%?) | Max. 0·5%(²) | Max. 0·5%(7) | not specified |
| | Melting Point | 146-148°(!) | 100-101(5) | 96-97°C(*) | Min. 50°C |
| SUS | Purity | Min. 99 · 0 %(?) | Min. 98 - 5 %(?) | Min. 98 · 5 %(?) | Min. 98-5% not less than 90-0% of the 3-isomer. |
| ANTIOXIDANTS | Description | Thite to creamy- white crystal- line powder, od our less, taste slightly bitter. | thito to creamy- white solid, o d our less, o dour less, bitter. | White to creamy- white solid, odourless, taste slightly hitter. | Vinto or slightly yellow waxy crystalline solid with an a r o m a t i c odour. |

282-20

COOCLH1

CuHnO,

338.20

COOCHES

C19H19O

DODECYL GALLATE

HO Y

180-25

CuHiO2

HYDROXY-ANISOLE (B.H.A.)

Molecular Weight

> Structural Formula COOC,H,

Empirical Formula CteHtsOs

212-20

| APPENDIX | |
|----------|--------|
| | |
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| | |
| | |
| | |
| | ANTS |
| | EXOL |
| | NA AC |
| | NS F |
| | CATIC |
| | PECIFI |
| | Ü. |

| | | SPECIF | CATIONS F | SPECIFICATIONS FOR ANTIOXIDANTS | NTS | | | |
|--------------|----------------------------|--|------------------------------|--|---|---------------------------------|-------------------------------|--|
| Antioxidant | Empirical Formu | Structural Formula | Molecular Weight | Description | Purity | Boiling | Refraetive | Solubility |
| ЕТНОХУДИІМ | Ci.Hr.3NO | CH ₁ O | 217-3 | Light number of No. leve than 127C at 1-59 to 10 10 10 10 10 10 10 1 | Not less than 92 per cent. by weight of the monomer. Remainder consists of the dimer and higher polymers. | 125°C at 1–2 mm. mercury. | 1-569 to 1-572 at 25°C. | presoluble in water. Soluble in organic solvents, and oils and fats. |
| Norz.—The li | Norg.—The limits for Arsen | (i) After deping at 110°C for 4 bours. (ii) After deping at 60°C for 4 bours. (iv) After deping at 60°C for 4 bours. (iv) After deping at 60°C for 4 bours. (iv) After deping at 60°C for 4 bours. | r 4 hours. c Arsenic in F | (f) After dr. ood Regulations 1 | (7) After drying at 60°C for 4 hours. Agulations 1959 and the Lend in Fo | 4 hours. nd in Food Reg | ulations 1961 res | spectively, i.e., |

APPENDIX III

Information and/or representations, oral or written, have been received from the following organisations and other interests concerned with the use of antioxidants in food-

Agricultural Attaché, American Embassy,

Association of Cereal Food Manufacturers Ltd.

Association of Public Analysts.

J. Bibby and Sons Ltd.

British Essence Manufacturers' Association.

British Food Manufacturing Industrial Research Association. British Glues and Chemicals Ltd.

British Plastics Federation.

Cake and Biscuit Alliance Ltd.

J. M. Collett and Co. Ltd.

Comet Rice Mills, Texas. John Crampton and Co. Ltd.

Distillers Co. Ltd.

East Malling Research Station.

F. M. S. (Farm Products) Ltd.

Food Manufacturers' Federation Incorporated.

Glaxo Laboratories Ltd.

Glutamates Ltd.

H. J. Heinz Company Ltd.

Home Grown Fruits Ltd.

Imperial Chemical Industries Ltd.

John Mackintosh & Sons Ltd.

May and Baker Ltd.

Medical School, University of Birmingham.

Monsanto Chemicals Ltd.

M. P. P. (Products) Ltd. National Association of Soft Drink Manufacturers Ltd.

National Farmers' Union. National Federation of Fruit and Potato Trades Ltd.

National Federation of Meat Traders' Association.

Office of the High Commissioner for Australia. Provision Importers' Association.

Roche Products Ltd.

Sova Foods Ltd.

Herbert Smith and Co. Wm. J. Stange Co. Chicago.

The Wrigley Company. University of Cambridge and Agricultural Research Council.

U.S. Packers Provision Agents' Committee.

Wallerstein Company.

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